

## **REMARKS**

Applicants have read and considered the Office Action dated September 24, 2004, and the references cited therein. By the present amendment, claims 1, 2 and 37 have been cancelled, without prejudice or disclaimer, new claims 3, 4, 6 to 10, 15 to 17, 19, 21 to 22, 44, 51 and 59 to 60 have been amended and claims 75-76 have been added. Claims 5, 18, 28 to 36, 54 to 58, and 61 to 74 have been withdrawn from consideration.

Support for the amendments to claims 4, 6-7 and 59-60 can be found throughout the specification, at least on page 22, line 21 of the application as originally filed. Support for the newly added claims can also be found in the specification, at least in the Sequence Listing and in originally filed claims 6 and 7.

No new matter has been added by the amendments.

### ***Objections to the specification.***

The disclosure was objected to because it contained an embedded hyperlink or other form of browser-executable code on page 23, 4<sup>th</sup> paragraph. The objected to paragraph has been replaced by a paragraph without a hyperlink or browser-executable code. Applicants assert that the objection to the specification is overcome.

### ***Claim objections.***

Claims 1-4 and 6-7 were objected to for reading on non-elected inventions. Claims 1 and 2 have been cancelled and claims 3-4 and 6-7 have been amended to remove reference to non-elected inventions. Applicants assert that the objection to the claims is overcome.

### ***Claim Rejections Under 35 USC §112***

Claims 19-24, 37, 44-45 and 51-52 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, claim 19 was rejected for reciting the limitation “said transformed plant” for which there was insufficient antecedent basis.

Claim 37 was rejected for merely reciting a use without any active, positive steps delimiting how this use is actually practiced. Claims 44 and 51 were rejected as being incomplete for omitting essential steps, i.e. the step for regenerating a plant from transformed tissue, as required by the preamble of the claim.

Claim 19 has been amended by inclusion of a step requiring the regeneration of a transformed plant from the transformed tissue, thereby providing ample antecedent basis for the recitation of “said transformed plant” later in the claim.

Claim 37 has been cancelled.

The preamble of Claims 44 and 51 has been amended to read “a method of modifying the regenerative capacity of a plant tissue”. Consequently, the step of regenerating a plant from the tissue is no longer required.

Applicants assert that the rejections under 35 U.S.C. § 112 are overcome. Withdrawal of these rejections in view of the amendments is respectfully requested.

#### ***Claim Rejections- 35 USC §101***

Claim 37 was rejected under 35 U.S.C. §101 because the claimed recitation of a use without setting forth any steps involved in the process results in a claim that is not a proper process claim under 35 U.S.C. §101.

Claim 37 has been cancelled without prejudice or disclaimer. Applicants assert that the rejection is moot.

#### ***Written description***

Claims 1-4, 6-7, 10-17, 19-27, 37-53 and 59-60 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) at the time the application was filed were in possession of the claimed invention.

Claims 1-2 and 37 have been cancelled. In as far as the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

In the Office Action, there were two main issues presented in the written description rejection.

The first issue relates to the polypeptides encoded by SEQ ID Nos: 1 and 3, which are supposed to be represented by SEQ ID Nos: 2 and 4 respectively, and which are described in the specification as being 97% similar at the amino acid level, while the polypeptides disclosed in SEQ ID Nos: 2 and 4 are identical.

Applicants thank the Examiner for identifying this unintentional error. The amino acid sequence of the polypeptides encoded by SEQ ID No 1 (BMN3A) and 3 (BMN3B) respectively are different in a number of amino acid positions, as can be seen e.g. from Figure 3 in the specification.

By the current amendment, the sequence listing wherein the amino acid entry in SEQ ID No 4 has been replaced by the correct amino acid sequence of BMN3B as can be found in Figure 3. No new matter has been added.

As the second issue, the Action indicated that Applicants did not identify essential regions of the proteins encoded by SEQ ID No 1 or 3, nor do Applicants describe any polynucleotide sequence that hybridize to a fragment of SEQ ID No 1 or 3 that encodes a protein with the same function as the protein encoded by SEQ ID No 1 or 3. Referring to University of California v. Eli Lilly and Co., 119 F. 3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), the Examiner maintains that the specification did not provide a representative number of DNA molecules defined by nucleotide sequence nor a recitation of structural features common to a member of the genus, which features constitute a substantial portion of the claimed genus. In other words, the specification failed to provide an adequate written description to support the breadth of the claims.

In as far as the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

The amended claims are drawn to isolated DNA molecules encoding a protein having at least 95% sequence identity with the amino acid sequences of the two exemplified polypeptides, isolated DNA molecules encoding the exemplified polypeptides, isolated DNA molecules having 95% sequence identity to the exemplified cDNAs, as well as vectors incorporating such isolated DNA molecules, methods employing such DNA molecules or plant cells, plants and seeds incorporating such DNA molecules.

Applicants would like to point the Examiner's attention to In Re Wallach, where the CAFC held that "*a claim to a genus of DNA molecules complementary to the RNA having the sequences encompassed by that formula, even if defined only in terms of the protein sequence that the DNA molecules encode, which containing a large number of species, is definite in scope and provides the public notice required of patent applicants* (emphasis added)" and further also "*Moreover, we see no reason to require a patent applicant to list every possible permutation of the nucleic acid sequence that can encode a particular protein for which the amino acid sequence is disclosed[...]*". In other words, the current specification clearly provides written description for the genus of isolated DNA molecules encoding polypeptides as defined in SEQ ID No 2 or 4.

However, Applicants would also like to point the Examiner's attention to the Synopsis of the Application of Written Description Guidelines, as available on the USPTO website, and which was recently found persuasive by the court of Appeals for the Federal Circuit. Of particular importance is Example 14, including a claim to a protein and variants thereof, that are at least 95% identical to that protein, and having the same function, even though "the specification contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitution, deletions, insertions and additions". Example 14 of the Synopsis also sets forth the premise that the specification provides an assay for detecting the catalytic activity of the protein. Applicants respectfully submit that likewise the current specification provides for methods to analyze the function of the encoded polypeptides. For

example, on page 29, it is said that transgenic explants constitutively expressing a protein of this class will be able to regenerate in the absence of added growth regulator (see also Example 5).

Combining the holding of In Re Wallach, and the USPTO's own guidelines on written description, one must reasonably come to the conclusion that a specification setting forth the amino acid sequence of a polypeptide and provides an assay for the functionality of such polypeptide, provides more than sufficient written description for claims directed towards the genus of isolated DNA molecules encoding a functional polypeptide having 95% sequence identity to the exemplified polypeptide. The claims clearly meet this level of identity.

Withdrawal of the rejection for the amended claims is therefore respectfully requested.

#### *Scope of enablement*

Claims 1-4, 6-7, 10-17, 19-27, 37-53 and 59-60 were rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for an isolated DNA molecule comprising SEQ ID No. 1 encoding SEQ ID No. 2 or SEQ ID No 3 or encoding SEQ ID No 4 and vectors or methods using such isolated DNA molecules, allegedly does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate with the claims.

Claims 1, 3 and 37 have been cancelled. In as far as the rejection still applies to the amended claims, Applicants respectfully traverse the rejection.

A first part of the contention supporting the rejection pertains to the use of so-called “hybridization language” in the claims directed towards isolated DNA molecules. Since the objected to hybridization language has been deleted from the claims by the current amendment, Applicants assert that this part of the rejection is moot.

The method claims were further rejected as being drawn to transiently transforming a plant cell with the vector of claim 10 as Applicants have only disclosed examples in which plants or plant cells are stably transformed with a nucleic acid molecule, and further in the light of contention in the Office Action that when nucleic acid molecules are not integrated into the plant

cell's genome, the introduced DNA would not be transferred to progeny cells and as such, would not affect the development of these cells.

Applicants respectfully disagree that for the development of the cells to be altered in accordance with the invention, the introduced DNA need to be stably transferred to progeny cells.

As indicated in the specification, at least on page 29, third paragraph, BNM3 as a transcriptional activator can initiate a developmental cascade in plant cells, and once initiated, the BNM3 activator need no longer be there. Hence the cascade may arise as a result of the transient expression of BNM3 from the transiently introduced vector.

The Action further indicates that Applicants have not disclosed how to make or isolate any of the sequences encompassed by Applicants' broad claims. In as far as this part of the rejection still applies to the amended claims, it is respectfully traversed.

The specification exemplifies two polypeptides that are 97% identical at the amino acid level (Figure 3) as well as the isolation of another polypeptide (and encoding DNA; *AtBBM*) from another species.

Applicants submit that this provides more than ample guidance for the skilled artisan to practice the invention without undue experimentation as recited in the amended claims.

Withdrawal of the rejection is therefore respectfully requested.

#### ***Claim Rejections- 35 USC §101***

Claim 17 was rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as it is unclear that the claimed seeds of the transformed plant would be distinguishable from seeds that occur in nature, in view of Mendelian inheritance of genes.

Applicants assert that amendment of claim 17 in accordance with the courteous suggestion by the Examiner overcomes the rejection.

***Claim Rejections- 35 USC §102***

Claims 1 and 3 were rejected under 35 U.S.C. § 102(b) as being anticipated by Elliot et al.

Claim 1 has been cancelled without prejudice or disclaimer, while claim 3 has been amended. In as far as the rejection applies to the amended claims, it is respectfully traversed.

As a first distinction with the nucleotide sequence described by Elliot et al. and the claimed subject matter of claim 3, Applicants point out that there is no evidence presented or suggested by Elliot et al. that the DNA molecule described therein when present at a sufficient level within a plant cell would render that cell embryogenic and/or increase the regenerative capacity of that plant cell. However, irrespective of the former argument, Applicants would also like to direct the Examiner to the attached alignments between the nucleotide sequence disclosed by Elliot and the nucleotide sequences entered as SEQ ID NO: 1 or 3 of the current application, which indicate that the latter sequences only share about 77% nucleotide sequence identity over a relative small part of the total sequences. The nucleotide sequence described by Elliot et al, therefore does not anticipate claim 3, which requires at least 95% nucleotide sequence identity.

Withdrawal of the rejection is therefore respectfully requested.

Claims 2, 4, 6-17, 19-27, 37-53 and 59-60 were deemed free of the prior art, and Applicants respectfully assert that this still applies to the claims as amended.

Finally, claims 8 and 9 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants thank the Examiner for the indication of allowable subject matter.

Applicants have rewritten claims 8 and 9 in independent form. However, in view of the limitation of the claim to a particular amino acid sequence, it is respectfully submitted that these claims should still be found allowable without any of the limitations of the base claim and any intervening claims.

A speedy and favorable action on the merits is hereby solicited. If the Examiner feels that a telephone interview may be helpful in this matter, please contact Applicant's representative at (612) 336-4728.



Respectfully submitted,

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